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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/812,884	03/21/2001	Russell John Mumper	50229-262	1135

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/21/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/812,884

Applicant(s)

MUMPER ET AL.

Examiner

Micah-Paul Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-33 is/are pending in the application.
- 4a) Of the above claim(s) 31-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Acknowledgment of Papers Received: Amendment and Response filed 8/28/03.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 21-23, 27, and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Ribier et al (USPN 5,658,575 hereafter referred to as '575). The claims are drawn to a method of making a nanoparticle comprising making an oil-in-water emulsion comprising a surfactant and a molecule of interest. The method further comprises heating the oil-in-water emulsion and then cooling it at room temperature.

'575 discloses a method for making a nanoparticle comprising making an oil-in-water emulsion comprising a surfactant and a molecule of interest (abstract). The oil-in-water emulsion comprises hydrophilic surfactants such as polyoxyethylene sorbitan fatty acids (col. 3, lin. 42 – 60), and molecules of interest such as vitamins and pharmaceutically active agents (col. 4, lin. 56 – col. 5, lin. 30). The nanoparticles have an average mean particle size below 200 nm (col. 3, lin. 15 – 25). The particles are formed by mixing the surfactant with the molecule of interest, heating the oil-in-water emulsion to a temperature between 20 and 90 degrees Celsius and

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cooling the resultant at room temperature while stirring (col. 6, lin. 10 – col. 7, lin. 10). These disclosures among others render the claims anticipated.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 24 – 26, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ribier et al (USPN 5,658,575 hereafter referred to as '575). The claims are drawn to a method of making a nanoparticle comprising making an oil-in-water emulsion comprising a surfactant and a molecule of interest. The method further comprises heating the oil-in-water emulsion and then cooling it at room temperature.

As discussed above '575 discloses a method for making a nanoparticle comprising making an oil-in-water emulsion comprising a drug and a surfactant, heating the emulsion, cooling the resultant to achieve a nanoparticle with average size below 300 nm (abstract). The reference however lacks some of the specific concentrations recited in the claims.

Regarding claims 24, 26, 28 and 29 it is the position of the examiner that such limitations do not impart patentability on the claims, and in light of the prior art can be determined through

routine experimentation. '575 discloses the essential elements of the invention. Applicant is reminded that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various nanoparticle compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

With regard to claim 25, it is the position of the examiner that the limitation does not impart patentability on the claim. It is the position of the examiner that in view of the prior art, a skilled artisan would be able to use the procedures disclosed in '575 to achieve a particle size below 100 nm. Though not enumerated in the particular reference a skilled artisan would be motivated to continue to reduce the particle size of the nanoparticle composition in order to increase the surface area and bioavailability of the resultant formulation.

With these things in mind a skilled artisan would have been motivated to follow the suggestions and teachings of the prior art in order to optimize the nanoparticle of '575. A skilled artisan would have been motivated to follow the teachings of '575 to modify and optimize the concentrations of the surfactant and molecule of interest. A skilled artisan would have been motivated to continue to reduce the particle size of the nanoparticle formulation in order to increase the surface area and increase the bioavailability of the formulation. It would have been

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obvious to a skilled artisan to modify the teachings and suggestions of the art with an expected result of a process for making an improved nanoparticle with improved bioavailability.

Response to Arguments

6. Applicant's arguments with respect to claims 21-30 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is 703-746-7648.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young
Examiner
Art Unit 1615

MP Young

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600